

3.0 510(k) SummaryPage 1 of 1

Sponsor: Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6940

MAR 28 2007

Contact: Sheri L. Musgnung
Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6940

Device Name: Synthes 4.5 mm LCP Posterolateral Proximal Femur Plate

Classification: ~~Class II~~, §888.3030 – Single/multiple component metallic bone fixation appliances and accessories

Predicate Device: Synthes LCP Proximal Femur Plate
Synthes 7.3 mm Cannulated Screws

Device Description: Synthes 4.5 mm LCP Posterolateral Proximal Femur Plates are contoured to match the anatomy of the proximal femur. The plates feature a limited-contact profile and Combi holes (Dynamic Compression Plate holes combined with locking screw holes), which accept 4.5 mm cortex, 5.0 mm locking screws, 5.0 mm cannulated locking screws, 7.3 mm cannulated locking screws, and 7.3 mm cannulated conical screws. The plates are manufactured from stainless steel and titanium.

Intended Use: Synthes 4.5 mm LCP Posterolateral Proximal Femur Plates are intended for treatment of fractures of the femur including: Basilar neck fractures such as Pauwels Type 3; fractures of the trochanteric region, trochanteric simple, cervicotrochanteric, trochanterodiaphyseal, multifragmentary pertrochanteric, intertrochanteric, intertrochanteric reversed or transverse or with additional fracture of medial cortex; fractures of the proximal end of the femur combined with ipsilateral shaft fractures, metastatic fractures of the proximal femur; and also for use in fixation of osteopenic bone and fixation of non-unions or malunions.

**Substantial
Equivalence:** Information presented supports substantial equivalence.

000005



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Synthes (USA)
% Ms. Sheri L. Musgnung
Senior Regulatory Affairs Specialist
Synthes (USA)
1301 Goshen Parkway
West Chester, Pennsylvania 19380

MAR 28 2007

Re: K070208

Trade/Device Name: 4.5mm LCP Posterolateral Proximal Femur Plate

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliance and accessories

Regulatory Class: Class II

Product Code: HRS

Dated: January 18, 2007

Received: January 22, 2007

Dear Ms. Musgnung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

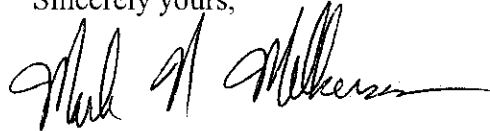
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Sheri L. Musgnung

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



2.0

Indications for Use

510(k) Number (if known):

K070208

Device Name:

Synthes 4.5 mm LCP Posterolateral Proximal Femur Plates

Indications for Use:

Synthes 4.5 mm LCP Posterolateral Proximal Femur Plates are intended for treatment of fractures of the femur including:

- Basilar neck fractures such as Pauwels Type 3,
- Fractures of the trochanteric region, trochanteric simple, cervicotrochanteric, trochanterodiaphyseal, multifragmentary pertrochanteric, intertrochanteric, intertrochanteric reversed or transverse or with additional fracture of medial cortex;
- Fractures of the proximal end of the femur combined with ipsilateral shaft fractures, metastatic fractures of the proximal femur; and
- Also for use in fixation of osteopenic bone and fixation of non-unions or malunions.

Prescription Use X
(Per 21 CFR 801.109)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

000004

510(k) Number _____

K070208